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IN THE

Supreme Court of the United States

WHOLE WOMAN'S HEALTH, *et al.*,

Petitioners,

KIRK COLE, COMMISSIONER, TEXAS DEPARTMENT OF STATE HEALTH SERVICES, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR *AMICUS CURIAE* FACILITY GUIDELINES INSTITUTE IN SUPPORT OF NEITHER PARTY

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INTEREST OF AMICUS CURIAE[1]

The Facility Guidelines Institute ("FGI") is a not-for-profit, nonpartisan § 501(c)(3) corporation dedicated to the development and promotion of evidence-based, physical design standards for healthcare facilities (the "Guidelines"). Founded in 1998 to take over the stewardship of the Guidelines that had previously been developed inside the federal government, FGI manages the Guidelines development process, protects the intellectual property of the Guidelines, and manages funding of research supporting the Guidelines development and distribution. In so doing, FGI utilizes the combined expertise of medical practitioners, architects, engineers, builders, and public health officials to review and consensually revise the healthcare facility design specifications originally developed and administered by the U.S. Department of Health and Human Services pursuant to the now-discontinued hospital construction program under the Hill-Burton Act, Pub. L. No. 79-725, 60 Stat. 1040 (1946) (codified, as amended, at 42 U.S.C. §§ 291-291o (1976)). Four successive editions of the Guidelines (2001, 2006, 2010, and 2014), entitled Guidelines for Design and Construction of Hospitals and Outpatient Facilities, have been developed under the guidance of FGI. The latest edition of the Guidelines contains the most broadly adopted set of physical standards for the

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[1] Letters from the parties consenting to the filing of amicus briefs have been lodged with the Clerk of the Court. No counsel for a party authored this brief in whole or in part and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief.

design of healthcare facilities in the United States, having had some edition adopted in whole or in part by forty-two (42) states (although not Texas). Part 3.7 of the Guidelines (2014) set forth the standards for outpatient surgical centers (also referred to as "ambulatory surgical centers") and are of particular importance to this case.

Revised from time to time with input and consensus from a multidisciplinary team of experts of various disciplines, the Guidelines provide design standards aimed at providing physical spaces for different medical procedures consistent with medical safety requirements, facility cost constraints, and design considerations. By utilizing a consensus-based drafting process that relies on and leverages stakeholders' expertise, the Guidelines provide credible, reasonable, and evidence-advised design requirements that are widely used as a national standard for healthcare facility design.

In the district court in the instant matter, testifying experts on both sides relied on the Guidelines' standards for ambulatory surgical centers ("ASC") to support their positions against and for Texas' law requiring that abortions must be performed in a facility that at a minimum meet the standards for ASCs imposed by the Texas Legislature and the rules that implement such law, Act of July 12, 2013, 83rd Leg., 2nd C.S., ch. 1, 2013 Tex. Gen. Laws 4795 (codified at Tex. Health & Safety Code Ann. § 245.010(a)) (the "ASC Requirement"). This testimony is now part of the record. FGI submits this brief to aid the Court's understanding and interpretation of the Guidelines as they bear on the necessity for – or obstacles and burdens presented by – Texas' ASC Requirement.

SUMMARY OF ARGUMENT

To maintain the integrity and credibility of FGI's guidelines, FGI submits this brief to ensure that its Guidelines are appropriately referenced and relied on in this case.

First, FGI explains that for as long as it has been tasked with developing and publishing the Guidelines, the treatment of patients, with the exception of invasive procedures that penetrate the protective surfaces of a patient's body (*e.g.*, skin, mucous membranes, cornea) and needing to be performed in an aseptic field, has been permitted in any outpatient facility. A procedure that does not entail penetration of the protective surfaces is by definition not invasive and therefore not required, under FGI's Guidelines, to be performed in an ASC.

Second, FGI's Guidelines are not written to apply retroactively to existing facilities unless there is a change in the function of the space or a major renovation. Texas' decision to depart from that approach by categorically taking the opposite approach for abortion facilities alone – requiring them, but not other outpatient surgical facilities that Texas has previously licensed as ASCs, to categorically comply retrospectively with the latest iteration of Guidelines for ASCs – is not supported by FGI's Guidelines.

ARGUMENT

I. FGI HAS CLEAR REQUIREMENTS FOR WHAT PROCEDURES MUST BE PERFORMED IN AN ASC

The FGI Guidelines do not have a specific category called Ambulatory Surgery Center. The FGI Guidelines do have a specific category called "Outpatient Surgical Facilities" ("OSF"). *See* Facility Guidelines Inst., *Guidelines for Design and*

Construction of Hospitals and Outpatient Facilities (2014), at § 3.7.[2] Section 3.7-1.1.1 indicates that the requirements for Outpatient Surgical Facilities apply to those outpatient facilities where surgery is performed. The Guidelines do not define surgery, but they do define surgical facilities as those "designated and equipped for performing surgical or other invasive procedures[,]" *id.* at p. xxxvi, implying that surgery is an invasive procedure. And they define an invasive procedure as:

> A procedure that:
>
> - Penetrates the protective surfaces of a patient's body (e.g., skin, mucous membranes, cornea).
> - Is performed in an aseptic surgical field (i.e., a procedure site).
> - Generally requires entry into a body cavity.
> - May involve insertion of an indwelling foreign body.

Id. at p. xxxiv.

> The intent is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into a normally sterile site. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin would not be included in this definition.

Id. at p. xxxv. FGI understands that the vagina is an orifice normally colonized with bacteria. *See*

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[2] The Guidelines are available at: http://www.fgiguidelines.org/digitalcopy.php.

Bryan Larsen & Gilles R.G. Monif, *Understanding the Bacterial Flora of the Female Genital Tract*, Oxford Journals, Clinical Infectious Disease, Vol. 32, Issue 4 (2001), at 69, http://cid.oxfordjournals.org/content/32/4/e69.full.

Every edition of the Guidelines prior to 2014 required invasive procedures to be performed in an OSF, and defined invasive procedures as "procedure[s] that penetrate[] the protective surfaces of a patient's body (*e.g.*, skin, mucous membranes, cornea) and that is performed within an aseptic field." Facility Guidelines Inst., *Guidelines for Design and Construction of Hospitals and Outpatient Facilities* (2010), at § 3.7 and p. xxx.

The FGI Guidelines have provided since 1996 that procedures NOT covered by the definition above may be performed in any type of outpatient facility. In particular, FGI Guidelines do not restrict the administration of oral medications to an OSF.

II. TEXAS' FAILURE TO GRANDFATHER FACILITIES IS NOT SUPPORTED BY FGI'S GUIDELINES

The ASC Requirement imposes new building standards on existing Texas abortion facilities, requiring existing abortion facilities to meet the enhanced standards for new ASC construction. *See* 25 Tex. Admin. Code § 139.40 (implementing regulation setting forth the ASC requirements now applicable to all abortion facilities, including physical plant and construction requirements).

Texas' attempted reliance on FGI's Guidelines to support the ASC Requirement, on page 9 of Respondents' Brief in Opposition to Certiorari, ignores, without any stated justification, FGI's general rule that the standards set forth in the

Guidelines are intended for *new* facilities and that it is generally inappropriate to require the retrofitting of existing facilities with new ASC standards. *See* Facility Guidelines Inst., *Guidelines for Design and Construction of Hospitals and Outpatient Facilities* (2014), at § 1.1 1.2.2.

Furthermore, even assuming *arguendo* that Texas appropriately relied on FGI's Guidelines to support the ASC Requirement for newly constructed facilities, nothing in the Guidelines suggests any basis for imposing new requirements only on any particular subset of existing facilities.

FGI's Guidelines generally provide that its standards are only applicable to new facilities, and FGI's standards are inappropriately enforced against existing licensed facilities, much less on a basis that discriminates without health justification against a subset of facilities.

CONCLUSION

For all the foregoing reasons, in resolving this case, if the Court relies on FGI's guidelines it should do so consistent with the understanding of those guidelines presented above.

December 30, 2015

Respectfully Submitted,

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